



# DOCUMENTING ISO 9000

# CHARACTERISTICS OF A PROCESS

- ★ *Consists of at least three elements*
  - *inputs*
  - *process activity*
  - *output*
- ★ *Processes are horizontal, not vertical*

# PROCESS INPUTS

- ★ *Anything needed to get started*
- ★ *When researching, ask about the many types of inputs*
- ★ *Look for 'fingerprints'*

# PROCESS ACTIVITY

- ★ *What you do with what you get*
- ★ *The process statements should contain a verb*
- ★ *It summarizes the activity that makes up the process*

# PROCESS OUTPUTS

- ★ *Anything resulting from the process activity*
- ★ *Every activity has at least one output*
- ★ *Every output becomes an input to another process*

# PROCESS DISCONNECTS

- ★ *The point at which one process should have connected with another, but didn't*
- ★ *Somebody doesn't do something they should have done*
- ★ *Something is not working properly*

# PROCESS DISCONNECTS

- ★ *Every process disconnect presents an opportunity for process improvement*
- ★ *Look for clues to a process disconnect*

# HANDLING PROCESS DISCONNECTS

- ★ *Technical Communicators only document the process disconnects, they DO NOT fix them*
- ★ *Document the disconnects factually and objectively*

# PROCESS MAPPING: A PRELUDE TO DOCUMENTATION

- ★ *Clearly defines the process inputs and outputs*
- ★ *Shows the cross-function connects and disconnects*
- ★ *Provides the starting point for process documentation*
- ★ *Can be used to supplement the text*
  - *highly recommended by many consultants*

# PROCESS MAPPING: A PRELUDE TO DOCUMENTATION

\* *PROCESS MAPPING EXERCISE*



# DOCUMENTATION CHECKLISTS & ISO 9000

# ISO 9000 SERIES OF STANDARDS

## ★ *Three Quality Standards.*

- *ISO 9001 - Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing*
- *ISO 9002 - Quality Systems - Model for Quality Assurance in Production, Installation, and Servicing*
- *ISO 9003 - Quality Systems - Model for Quality Assurance in Final Inspections and Testing*

# ISO 9000 ELEMENT MATRIX

ELEMENT TITLE	FOUND IN THIS STANDARD		
	9001	9002	9003
4.1 Management Responsibility	✓	✓	✓
4.2 Quality System	✓	✓	✓
4.3 Contract Review	✓	✓	✓
4.4 Design Control	✓	—	—
4.5 Document and Data Control	✓	✓	✓
4.6 Purchasing	✓	✓	—
4.7 Control of Purchaser-Supplied Product	✓	✓	✓
4.8 Product Identification and Traceability	✓	✓	✓

# ISO 9000 ELEMENT MATRIX

ELEMENT TITLE	FOUND IN THIS STANDARD		
	9001	9002	9003
4.9 Process Control	✓	✓	—
4.10 Inspection and Testing	✓	✓	✓
4.11 Control of Inspection, Measuring, and Test Equipment	✓	✓	✓
4.12 Inspection and Test Status	✓	✓	✓
4.13 Control of Nonconforming Product	✓	✓	✓
4.14 Corrective and Preventative Action	✓	✓	✓
4.15 Handling, Storage, Packaging, Preservation, and Delivery	✓	✓	✓

# ISO 9000 ELEMENT MATRIX

ELEMENT TITLE	FOUND IN THIS STANDARD		
	9001	9002	9003
4.16 Control of Quality Records	✓	✓	✓
4.17 Internal Quality Audits	✓	✓	✓
4.18 Training	✓	✓	✓
4.19 Servicing	✓	✓	—
4.20 Statistical Techniques	✓	✓	✓

# ISO 9000 DOCUMENTATION CHECKLISTS

- ★ *Why are they used?*
  - *provide a roadmap through each element*
  - *allow large documentation tasks to be broken up amongst more than one person*
  - *ensure all bases are covered*
  - *provide a reference point for process improvements*
  - *form the basis for internal audits*

# WRITING ISO-COMPLIANT DOCUMENTATION

*Refer to your Documentation  
Checklist handout and we will  
write an ISO-compliant Level II  
procedure*

Workshop materials, transparencies, and handouts were prepared  
by

**R<sup>2</sup> INNOVATIONS**  
**5050 Willowood Drive**  
**Mississauga, Ontario, Canada**